

COUNT II

**ALLEGED DECEPTIVE TRADE PRACTICES
(Violations of Mont. Code. Ann. §§ 30-14-101-1414)**

**CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND
RESTITUTION FOR THE STATE OF MONTANA**

661. Answering for paragraph 661, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 660.

662. Denies that Plaintiff is entitled to maintain this action as alleged or to obtain any relief against AstraZeneca, and specifically denies the existence of, or participation in, any “AWP Inflation Scheme” and “Best Price Scheme,” as alleged in paragraph 662.

663. States that paragraph 663 (and its subparts) consists of conclusions of law to which no response is required, denies the allegations in paragraph 663 (and its subparts) to the extent that they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 663 (and its subparts) as to the other parties. Further, AstraZeneca refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff’s “Best Price” claims for all AstraZeneca drugs except Zoladex, and also refers to AstraZeneca’s settlement agreement with the State of Montana, executed in 2003, which releases and discharges any civil or administrative claims for Medicaid damages the State of Montana has or may have relating to Zoladex.

664-666. Denies the allegations in paragraphs 664-666 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraphs 664-666 as to the other parties.

667. States that paragraph 667 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 667 to the extent that they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 667 as to the other parties. AstraZeneca further denies that Plaintiff has suffered damages or injuries as alleged in paragraph 667.

667a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 667 of the SAC.

COUNT III

**ALLEGED MEDICAID FRAUD
(Violations of Mont. Code Ann. § 53-6-160)**

CLAIM FOR COST RECOVERY

668. Answering for paragraph 668, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 667.

669. Admits that Plaintiff purports to bring a claim for Medicaid cost recovery under Count III as alleged in paragraph 669, but denies that Plaintiff

may properly bring this lawsuit or obtain any relief against AstraZeneca under Count III.

670. Denies the allegations in paragraph 670, but admits that AZPLP is a manufacturer of drugs included in the Montana Medicaid drug formulary, and otherwise denies knowledge or information sufficient to form a belief as to the other parties.

671-675. Refers to the Court Order, dated June 10, 2004, which dismisses Plaintiff's Best Price claims for all AstraZeneca drugs except Zoladex, and also refers to AstraZeneca's settlement agreement with the State of Montana, executed in 2003, which releases and discharges any civil or administrative claims for Medicaid damages the State of Montana has or may have relating to Zoladex based upon the allegations of the SAC. Accordingly, no response is required to paragraphs 671-675. To the extent any response is required, AstraZeneca denies the allegations in paragraphs 671-675.

676. Denies the allegations in paragraph 676, to the extent they are directed at AstraZeneca, refers to AstraZeneca's settlement agreement with the State of Montana, executed in 2003, which releases and discharges any civil or administrative claims for Medicaid damages the State of Montana has or may have relating to Zoladex based upon the allegations of the SAC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 676 as to the other parties.

677-678. Denies the allegations in paragraphs 677-678 to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information

sufficient to form a belief as to the truth of the allegations in paragraphs 677-678 as to the other parties.

679. States that paragraph 679 consists of a conclusion of law to which no response is required, otherwise denies the allegations in paragraph 679 to the extent they are directed at AstraZeneca, and denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 678 as to the other parties.

679a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 679 of the SAC.

COUNT IV
ALLEGED FALSE CLAIMS
(Violations of Mont. Code. Ann. § 17-8-231)

**CLAIM FOR FORFEITURE, CIVIL PENALTIES, DOUBLE DAMAGES
AND LEGAL COSTS**

680. Answering for paragraph 680, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 679.

681. Admits that Plaintiff purports to bring this action and to seek relief pursuant to Mont. Code Ann. § 17-8-231 under Count IV as alleged in paragraph 681, but denies that Plaintiff may properly bring this lawsuit or obtain any relief against AstraZeneca under Count IV.

682. Denies the allegations in paragraph 682, except admits that AZPLP is a manufacturer of drugs included in the Montana Medicaid drug

formulary, and otherwise denies knowledge or information sufficient to form a belief as to the other parties.

683-687. The Court dismissed Count IV as it relates to Plaintiff's "Best Price" claims in its Order dated June 10, 2004. As such, AstraZeneca does not respond to paragraphs 683-687. To the extent a response is required, AstraZeneca denies all allegations contained in paragraphs 683-687.

688. Denies the allegations in paragraph 688 to the extent that they are directed at AstraZeneca and refers to AstraZeneca's settlement agreement with the State of Montana, executed in 2003, which releases and discharges any civil or administrative claims for Medicaid damages the State of Montana has or may have relating to Zoladex based upon the allegations of the SAC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations as to the other parties.

689-691. Denies the allegations in paragraphs 689-691, and refers to the Court Order dated June 10, 2004 dismissing Count IV as it relates to Plaintiff's "Best Price" claims, and refers to AstraZeneca's settlement agreement with the State of Montana, executed in 2003, which releases and discharges any civil or administrative claims for Medicaid damages the State of Montana has or may have relating to Zoladex based upon the allegations of the SAC, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations as to the other parties.

691a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following

paragraph 691 of the SAC, refers to the Court Order dated June 10, 2004 dismissing Count IV as it relates to Plaintiff's Best Price claims, and refers to AstraZeneca's settlement agreement with the State of Montana, executed in 2003, which releases and discharges any civil or administrative claims for Medicaid damages the State of Montana has or may have relating to Zoladex based upon the allegations of the SAC.

COUNT V

**ALLEGED PUNITIVE DAMAGES
CLAIM BROUGHT ON BEHALF OF THE STATE OF MONTANA**

692. Answering for paragraph 692, repeats and incorporates as if fully set forth herein each and every response to the allegations in paragraphs 1 through 691.

693. Denies the allegations in paragraph 693 (and its subparts) to the extent they are directed at AstraZeneca, and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 693 as to the other parties.

693a. Denies that Plaintiff is entitled to a judgment or any other relief requested in its prayer for relief, as stated in the unnumbered paragraph following paragraph 693 of the SAC.

XI. DEMAND FOR JURY TRIAL

AstraZeneca denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief.

DEFENSES

Without assuming the burden of proof of such defenses that it would not otherwise have, AstraZeneca asserts the following defenses:

First Defense

Plaintiff fails to state a claim against AstraZeneca upon which relief may be granted.

Second Defense

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of AstraZeneca as alleged in the Complaint.

Third Defense

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against AstraZeneca based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

Fourth Defense

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Montana.

Fifth Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

Sixth Defense

Any and all actions taken by AstraZeneca with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

Seventh Defense

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eighth Defense

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

Ninth Defense

Plaintiff's claims against AstraZeneca are barred because AstraZeneca has complied with all applicable regulations of the federal and state governments.

Tenth Defense

Plaintiff's claims against AstraZeneca are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

Eleventh Defense

Plaintiff's claims are barred, in whole or in part, because they violate AstraZeneca' rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Montana, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

Twelfth Defense

AstraZeneca's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

Thirteenth Defense

Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multi source medicine allegations against AstraZeneca contained in the Complaint.

Fourteenth Defense

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including but not limited to, Plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

Fifteenth Defense

Plaintiff fails to allege with particularity its civil conspiracy claims against AstraZeneca as required by FED. R. CIV. P. 9(b).

Sixteenth Defense

Plaintiff's claims against AstraZeneca are barred because AstraZeneca did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

Seventeenth Defense

Plaintiff's claims against AstraZeneca are barred, in whole or in part, because AstraZeneca did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against AstraZeneca that Plaintiff alleges to be false or misleading, AstraZeneca had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Eighteenth Defense

Plaintiff's claims against AstraZeneca are barred because AstraZeneca did not directly or indirectly engage in any conduct in violation of state or federal law.

Nineteenth Defense

AstraZeneca denies that Plaintiff has valid consumer protection claims against AstraZeneca under Montana state law. However, if such claims are found to exist, AstraZeneca pleads all available defenses under the applicable laws.

Twentieth Defense

Any allegedly fraudulent statements or conduct of AstraZeneca did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Montana.

Twenty-First Defense

AstraZeneca' conduct was not "deceptive" as required under Montana consumer protection laws.

Twenty-Second Defense

To the extent that Plaintiff seeks equitable relief against AstraZeneca, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

Twenty-Third Defense

Plaintiff did not rely on the allegedly fraudulent statements or conduct of AstraZeneca as required under the Montana consumer protection laws.

Twenty-Fourth Defense

Any allegedly fraudulent statement or conduct of AstraZeneca was not consumer-oriented as required under the Montana consumer protection laws.

Twenty-Fifth Defense

Plaintiff's claims against AstraZeneca for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

Twenty-Sixth Defense

Some or all of Plaintiff's claims for injunctive relief against AstraZeneca are barred by the doctrines of *in pari delicto* and/or unclean hands.

Twenty-Seventh Defense

Some or all of Plaintiff's claims against AstraZeneca arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

Twenty-Eighth Defense

Plaintiff's claims against AstraZeneca are barred, in whole or in part, due to its failure to join indispensable parties.

Twenty-Ninth Defense

Plaintiff's claims against AstraZeneca are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

Thirtieth Defense

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

Thirty-First Defense

Plaintiff's claims against AstraZeneca for damages are barred, in whole or in part, because: (1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to AstraZeneca; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by AstraZeneca after the filing of Plaintiff's original Complaint; and (4)

Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

Thirty-Second Defense

AstraZeneca is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

Thirty-Third Defense

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from AstraZeneca.

Thirty-Fourth Defense

Plaintiff fails to allege facts or a cause of action against AstraZeneca sufficient to support a claim for attorneys' fees, double damages and/or legal fees.

Thirty-Fifth Defense

Plaintiff's punitive damages claims against AstraZeneca: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against AstraZeneca; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give AstraZeneca prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of AstraZeneca's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the Constitution of the State of Montana; (4) cannot be sustained because any award

of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Montana; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against AstraZeneca for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of AstraZeneca's medicines, would constitute impermissible multiple punishments for the same wrong in violation of AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Montana; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate AstraZeneca's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according AstraZeneca the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-

incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate AstraZeneca's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana.

Thirty-Sixth Defense

Plaintiff's claim for punitive damages against AstraZeneca cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of AstraZeneca; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate AstraZeneca's

Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Montana.

Thirty-Seventh Defense

Plaintiff's claim for punitive damages against AstraZeneca cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate AstraZeneca's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate AstraZeneca's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Montana.

Thirty-Eighth Defense

Some or all of Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Thirty-Ninth Defense

Plaintiff's fraud-based claims and Plaintiff's claims of fraudulent concealment are barred because Plaintiff knew or should have known before the filing of the complaint that published AWPs do not represent actual averages of the prices at which providers or pharmacies are able to purchase drugs.

Fortieth Defense

AstraZeneca adopts by reference any additional applicable defense pled by any other defendant in this case, not otherwise pled herein.

Forty-First Defense

Plaintiff's "Best Price" claims with respect to all AstraZeneca drugs other than Zoladex, as well as Plaintiff's "Best Price" claims relating to Zoladex in Count IV, are barred by the Court Order dated June 10, 2004.

Forty-Second Defense

Plaintiff's claims relating to Zoladex are barred by the settlement agreement between Plaintiff and AstraZeneca, executed in 2003, which discharged and released all civil and administrative claims for Medicaid damages or penalties that Plaintiff may have relating to Zoladex based on the allegations of the SAC.

Forty-Third Defense

AstraZeneca hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserves its right to amend its answer to assert such defense.

WHEREFORE, AstraZeneca prays that this Court:

1. Dismiss Montana's Second Amended Complaint with prejudice and enter judgment in favor of AstraZeneca against Plaintiff;
2. Award AstraZeneca its costs and expenses; and

3. Grant such other and further relief for AstraZeneca as this Court deems just and proper.

July 12, 2004

/s/ Lucy Fowler

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CERTIFICATE OF SERVICE

I certify that on July 12, 2004, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

/s/ Lucy Fowler

Lucy Fowler